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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CARTER, KENDRA D	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/392,842	SAWAN ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58,60,62-71,89,91-94 and 96-125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58,60,62-71,89,91-94 and 96-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 58, 60, 62-71, 89, 91-94 and 96-125 are pending in the application and are being examined on the merits herein.

It is noted that the claims are being examined to the extent they read on the elected species of biguanide polymer (cationic polymer) that is poly(hexamethylenebiguanide) ("PHMB"), and the water-insoluble organic compound that is methylene-bis-N,N-diglycidylaniline, ("MBDGA").

The Examiner acknowledges Applicant's indication that a terminal disclaimer will be filed upon identification of allowable subject matter to obviate the provisional obviousness-type double patenting rejections over U.S. Patents 6,180,584; 6,030,632; 5,869,072 and 5,817,325. However, as such terminal disclaimers have not as-yet been filed, the provisional obviousness-type double patenting rejections over these co-pending applications are being maintained.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 as being unpatentable over Morlet et al. in

view of Fox, Jr., and further in view of Smith were found not persuasive, thus the rejection is upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 65-67, 91, 94, 97, 104,107 and 115-116 as being unpatentable over Morlet et al. in view of Fox, Jr., and further in view of Smith as applied to claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 above, and further in view of Sawan et al., were found not persuasive, thus the rejection is upheld.

In light of no amendments to the claims, the previous 35 U.S.C. 103(a) rejections and obviousness double patenting rejections is repeated below. Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and 117-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morlet et al (WO 97/00076), in view of Fox, Jr. (U.S. Patent No. 5,374,432), and further in view of Smith (U.S. Patent No. 5,576,006).

Morlet et al. teaches compositions comprising poly(hexamethylene biguanidine) salts in the topical treatment of microbial infections, as well as in pharmaceutical preparations and antiseptics (see abstract, in particular.) Morlet et al. teaches that PHMB has been discovered to be generally useful for the topical treatment of microbial infection of the human or animal body, such as on skin, as well as an antiseptic to clean skin (see page 3, lines 20-30, page 4, lines 18-25, and page 6, lines 30-35, in particular.) Morlet et al. teaches that compositions applied to the skin can comprise aqueous formulations, oily formulations, an oil-in-water emulsion, and a gel formulation, among others, and thus teaches the carrier and formulation form as recited in claims 58, 89, 92, 103, 105 and 109 (see page 7, lines 3-8, in particular.) Morlet et al. also teaches that the composition can comprise excipients to adjust the viscosity (thickeners) (see page 9, lines 25-35, in particular), and thus teaches the skin-compatible component as recited in claim 93. Accordingly, Morlet et al. teaches a method for providing improved antimicrobial activity on skin comprising administering to the skin a composition comprising a polymer corresponding to the elected species of poly

(hexamethylenebiguanide) (PHMB), as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105.

Regarding claims 96, 98 and 108, it is noted the Moret et al. exemplifies bathing tissue in PHMB solution (see Example 4, in particular), and thus teaches that the composition can be administered by immersion, as recited in the claims.

Morlet et al. does not specifically teach administering to the skin a composition comprising an antimicrobial metallic material, as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105. Morlet et al. also does not specifically teach forming a moisture-resistant film on the skin, as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105. However, Morlet et al. does teach that the composition can comprise further pharmaceutically active substances, such as other compositions having antimicrobial activity (see page 10, lines 18-26, in particular.)

Fox teaches topical compositions having silver or a silver salt along with an antibiotic (see abstract, in particular.) Fox teaches that it is known to provide silver salts to prevent or reduce the infection of burn wounds, and that silver salts such as AgSD are known to be effective against a number of different types of bacteria (see column 1, lines 15-25, and column 2, lines 10-30, in particular.) Fox teaches that it has been further discovered that combinations of silver or silver salts with other antimicrobials provide improved antimicrobial efficacy, such that lower levels of the other antimicrobial

agents can be provided (see column 1, lines 25-33 and column 2, lines 30-45, in particular.) Fox teaches that suitable silver salts include silver iodide and silver nitrate (see column 1, lines 60-66, in particular), and thus teaches the antimicrobial metallic materials as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105. Fox teaches that composition having the silver or silver salt and antimicrobial agent can be administered for ocular infections as well as in the treatment of burn wounds (see column 2, lines 10-30, in particular), and thus Fox teaches that the silver or silver salts can be administered topically to skin.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the antimicrobial silver salt of Fox in the topical application method and composition of Morlet et al, because Morlet et al. teaches topically administering a composition having an antimicrobial agent for the treatment of microbial infections, and teaches the composition can also comprise other conventional antimicrobial agents, while Fox teaches that silver salts act as antimicrobial agents, are suitable for topical compositions, and exhibit synergistic effects with other antimicrobials. Thus, it is considered that one of ordinary skill in the art would have been motivated to provide the silver salts in the method and composition of Morlet et al. with the expectation of formulating a composition having the desired antimicrobial effects and even having improved antimicrobial effects due to the synergism of the silver salts with the antimicrobial agent. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be

useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Morlet et al. and Fox do not specifically teach forming a moisture-resistant film on the skin, as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105.

Smith teaches forming complexes of antimicrobial compounds that are less water soluble and more hypoallergenic (see abstract and column 1, lines 10-20, in particular.) Smith teaches that the complexes desirably form a more insoluble higher molecular weight molecule that posses the full activity of the smaller molecule, but are more resistant to being washed away, more hypoallergenic, and longer lasting, and thus allow a larger lasting effect without having to use the antimicrobial agent in higher dosages (see column 3, lines 10-25, in particular.) Smith teach that the complex can be used in body compositions such as powders, lotions or salves used in treating the body (see column 2, lines 34-38, in particular.) Smith teaches that, in particular, the antimicrobial complexes can be forming with antimicrobial biguanide compounds, such as polyhexamethylene biguanide hydrochloride (see column 2, lines 55-60 and column 4, lines 10-15, in particular), and thus teaches forming a complex from the elected species of biguanide polymer. Smith further exemplifies a preparation having a COSMOCIL (polyhexamethylene biguanide hydrochloride) and citrate complex, in which the high

molecular weight complex forms a film upon application to a surface (see Example 1, in particular.) Thus, Smith et al. teaches providing a polyhexamethylene biguanide complex that forms a moisture-resistant film, and thus imparts a persistant antimicrobial activity, as recited in claims 58, 89, 92, 93, 96, 98, 103 and 105.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the high molecular weight polyhexamethylene biguanide complex of Smith in the topical antimicrobial treatment method of Morlet et al. and Fox, because Morlet et al. and Fox teach that polyhexamethylene biguanide can be topically applied to skin to provide antimicrobial treatment, whereas Smith teaches that the antimicrobial use of polyhexamethylene biguanide, including use on the body, can be improved by forming a high molecular weight complex of the compound, which has higher water resistance, is more hypoallergenic, and is longer lasting. Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the polyhexamethylene biguanide complex in the method and composition of Morlet et al. and Fox, and thus to form a moisture-resistant film on the skin, with the expectation of providing improved antimicrobial activity that is longer lasting and more hypoallergenic. Accordingly, claims 58, 89, 92, 93, 96, 98, 103 and 105 are obvious over the teachings of Morlet et al. in view of Fox and Smith.

Regarding claims 60, 106 and 110-111, Morlet and Smith teach providing poly (hexamethylenebigaunide) and the hydrochloride salt thereof, as has been discussed above. Regarding claims 62-64, 101, 112-114 and 123, Fox teaches the silver salt can be silver nitrate or silver iodide, as discussed above.

Regarding claims 68-71 and 117-120, as Morlet et al. and Smith teach the same biguanide polymer as that of the instantly elected species, it is considered the Morlet et al. and Smith also teach a compound having the same chemical groups and the ability to form the covalent bonds at room temperature, as recited in the claims. It is noted that the a product and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Regarding claims 99-100 and 121-122, as Smith et al. teaches that the high-molecular complex of the biguanide polymer is water-resistant, it is considered that the film is also sweat resistant and does not leach into a contacting aqueous solution, as recited in the claims. Furthermore as the combined teachings of Morlet et al, Fox and Smith renders the composition used in the claims method obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the sweat resistance and resistance to leachability, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See

MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claims 102 and 124, as the combined teachings of Morlet et al, Fox and Smith renders the obvious the use of the same metallic material as recited in the claimed method, is it considered that the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the binding of the metallic materials to the cellular proteins of microorganisms, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

(2) Claims 65-67, 91, 94, 97, 104,107, 115-116 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/00076 to Morlet et al, in view of U.S. Patent No. 5,374,432 to Charles L. Fox, Jr., issued December 20, 1994, and U.S. Patent No. 5,576,006 to W. Novis Smith, issued November 19, 1996, as applied to claims 58, 60, 62-64, 68-71, 89, 92, 93, 96, 98-103, 105-106, 108-114 and

117-124 above, and further in view of WO 95/17152 to Sawan et al, published Jun 29, 1995.

Morlet et al, Fox and Smith are applied as discussed above, and teach a method of providing antimicrobial activity on skin by applying a composition having the elected species of polyhexamethylene biguanide hydrochloride and an antimicrobial metallic material, such as silver nitrate or silver iodide. Smith furthermore teaches the desirability of complexing the polyhexamethylene biguanide hydrochloride with another compound to provide a high molecular weight compound. Smith teaches that the formation of a higher molecular weight compound provides a compound that is more insoluble and is longer lasting since the newly formed molecule has increased size. Thus, the compound has improved resistance to being washed away and improved hypoallergenicity, and has a longer lasting effect (see column 3, lines 10-25 of Smith, in particular.) Smith also teaches an embodiment in which the improved antimicrobial composition forms a film (see Example 1, in particular.)

The references do not specifically teach forming an adduct of the biguanide with the elected species of substantially water-insoluble organic compound that is methylene-bis-N,N-diglycidylaniline, as recited in the claims.

Sawan et al. teaches that polyhexamethylene biguanide is known as an antibacterial and antimicrobial agent (see pages 19-20, in particular.) Sawan et al. also teaches that the antimicrobial compounds can be derivatized. Sawan et al. further teaches that a suitable antimicrobial combination that is effective against both bacteria and yeast can be a combination of silver and a biguanide compound (see page 22, first full paragraph, in particular.) Sawan et al. exemplifies an antimicrobial coating solution in which an adduct of polyhexamethylenebiguanide and 4,4-methylene-bi(N,N-diglycidylaniline) is formed (see Example 18, in particular), and thus teaches the elected species of substantially water-insoluble organic compound that is methylene-bis-N,N-diglycidylaniline, as recited in the claims. Sawan et al. also teaches silver iodide can be added to the exemplified solution (see Example 19, part (c), in particular.) Sawan et al. teaches that the antimicrobial compositions are suitable for sterilizing solutions such as eyecare liquids and other medicaments (see page 6 and page 9, in particular), and thus teaches that the antimicrobial compositions are safe for use with compositions meant for application to the body.

Accordingly, it is considered that one of ordinary skill in the art would have found it obvious at the time the invention was made to provide the PHMB and 4,4-methylene-bis(N,N-digylidylaniline) complex of Sawan et al. in the method and composition of Morlet et al, Fox and Smith, because Morlet et al, Fox and Smith teach the desirability of topically applying a composition having silver salts and PHMB to provide antimicrobial activity, and also teach that PHMB can be complexed with other

compounds to provide a higher molecular weight compound that is longer lasting in its efficacy, and Sawan et al teaches a PHMB complex that provides antimicrobial activity, is safe for use with compositions that are applied to the body, and can be advantageously combined with silver salts. Thus, it is considered that one of ordinary skill in the art would have been motivated to provide the PHMB complex of Sawan et al. in the composition and method of Morlet et al, Fox and Smith, with the expectation of providing an improved antimicrobial composition and method having an antimicrobial PHMB complex that can be suitably combined with the silver salts therein, that is safe for application to the body, and that is a high molecular weight complex with longer lasting antimicrobial activity.

Furthermore, regarding the formation of a film on the skin with the composition, as recited in the claims, it is considered that as Morlet et al, Fox, Smith and Sawan et al. render the claimed composition and method of using obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the formation of the film, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product and process of using the product.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58, 60, 62-71, 89, 91-94 and 96-125 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,180,584, claims 1-6 of U.S. Patent No. 6,030,632, claims 1-9 of U.S. Patent No. 5,869,072, and claims 1-9 of U.S. Patent No. 5,817,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the cited patents are directed to compositions comprising a biguanide

material, a metal material such as silver compounds and a cross linker and/or methods of using such composition to improve antimicrobial activity of an article or a secondary formulation.

For example, the claims of the patent 6,018,584 are directed to methods of providing antimicrobial activity on skin by applying the claimed invented disinfectant composition of a substrate (claims 1, 27-33.) The instant claims differ from the patented claims only by the nature of the substrate. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the composition of the patented claims on suitable substrates including scrubs, skin preparations directly or through suitable carrier systems. Accordingly, the instant claims are an obvious modification of the already patented claims.

Response to Arguments

Applicant's arguments and declaration filed May 28, 2008 have been fully considered but they are not persuasive.

Declaration by Dr. Sawan

> The Declaration teaches that the present invention is directed to compounds that are water insoluble providing essentially no solubility in water, whereas Smith teaches complexes that are acid base salts or Coulombic complexes that can be expected to dissociate in aqueous environments. The current invention form emulsions or microemulsions in water therefore not forming a true solutions, but instead a film which has essentially no solubility in water as determined by analytical methods and microbiology testing. Additionally the invention provides for coordination complexation of antimicrobial meets to nitrogen ligands, which results in water insoluble complexes.

The Declaration is not persuasive to overcome the present rejections because Smith teaches that that the complexes desirably form a more insoluble higher molecular weight molecule that posses the full activity of the smaller molecule, but are more resistant to being washed away, more hypoallergenic, and longer lasting, and thus allow a larger lasting effect without having to use the antimicrobial agent in higher dosages (see column 3, lines 10-25). Particularly, the complexes are formed in an aqueous solution, but the active complex is a clear film which is active against bacteria (see column 4, example 1). Additionally, the complexes are precipitated out of the aqueous solutions (see examples 4 and 5). The Examiner would like to note that the claims do not limit how the complex is formed or the specific complex formed, but its final characteristic of being substantially water insoluble, which is taught by Smith.

35 USC 103 rejections

> The Applicant argues that although Morlet, Smith and Fox each teach antimicrobial compositions, the art does not provide either the suggestion or desirability to combine the references in such a way to arrive at the present invention.

The Examiner disagrees because as stated in the previous office action, Morlet et al. and Fox et al. teach the desirability of providing topical antimicrobial compositions having the biguanide polymer and antimicrobial metallic material as claimed. Particularly, Morlet et al. teaches that PHMB has been discovered to be generally useful for the topical treatment of microbial infection of the human or animal body, such as on skin, as well as an antiseptic to clean skin (see page 3, lines 20-30, page 4, lines 18-25, and page 6, lines 30-35, in particular.) Fox et al. teaches that it is known to provide silver salts to prevent or reduce the infection of burn wounds, and that silver salts such as AgSD are known to be effective against a number of different types of bacteria (see column 1, lines 15-25, and column 2, lines 10-30, in particular.) Fox et al. further teaches that it has been further discovered that combinations of silver or silver salts with other antimicrobials provide improved antimicrobial efficacy, such that lower levels of the other antimicrobial agents can be provided (see column 1, lines 25-33 and column 2, lines 30-45, in particular.) Thus, motivation has been provided by Fox et al. to combine two antimicrobial. Particularly since the biguanide polymer is generally useful and the addition of silver salts improve antimicrobial efficacy. In re Kerkoven applies to the above combination because Morlet teaches the antibacterial film with the Applicant's biguanide polymer that can be combined with other antibacterial agents, and Fox teaches silver salts as an effective antibacterial that increases the efficacy of other antibacterial compositions. Thus both references teach topical antibacterial compositions those are proper to be applied to In re Kerkoven.

> The Applicant argues that the Examiner points to Fox's statement that the silver salts exhibit synergistic effects with other antimicrobials as motivation to combine each of Fox, Morlet, and Smith. However, other references disclose that combining antimicrobials do not provide a synergistic effect, and provide nothing more than a simple combination. The Applicant gives five examples of art that would lead a person skilled in the art to understand that this is an unpredictable area and any improvements would have to be determined by trial and error of the particular combinations of interest.

The Examiner disagrees because Example A and B are not commensurate in scope to the Fox reference. The above examples compare antimicrobials mixed with sodium salts, whereas the Fox reference is used to teach that combinations of silver or silver salts with other antimicrobials provide improved antimicrobial efficacy, such that lower levels of the other antimicrobial agents can be provided (see column 1, lines 25-33 and column 2, lines 30-45). The Examples D and E provide positive results, and Example C completely showed no statically significant difference in the outcome of mixing an antibiotic with silver nitrate. Therefore, the positive results in Examples D and E, as well as in the Fox references provides one skilled in the art to try the combination for the reasons provided by the references above.

> The Applicant argues that the claims limit the composition to be substantially water-insoluble or can be rendered substantially water-insoluble, and forming a moisture-resistant film on the skin. Smith teaches forming less water soluble compounds, no insoluble compositions. The Applicant relies upon the Declaration to teach the types of complex taught by the Smith reference versus the invention, which would render them different.

The Examiner disagrees because Smith teaches forming complexes of antimicrobial compounds that are less water soluble and more hypoallergenic (see abstract and column 1, lines 10-20). Smith teaches that the complexes desirably form a more insoluble higher molecular weight molecule that possess the full activity of the smaller molecule, but are more resistant to being washed away, more hypoallergenic, and longer lasting, and thus allow a larger lasting effect without having to use the antimicrobial agent in higher dosages (see column 3, lines 1-25). In particular, polyhexamethylene biguanide hydrochloride is taught as one of the compounds to form the complex (see column 2, lines 34-38). Thus teaching a film that is water-resistant and has persistent antimicrobial activity is taught with the applicant's elected compound. As stated above, the complexes are formed in an aqueous solution, but the active complex is a clear film which is active against bacteria (see column 4, example 1). Additionally, the complexes are precipitated out of the aqueous solutions (i.e. insoluble; see examples 4 and 5). The Examiner would like to note that the claims do not limit how the complex is formed or the specific complex formed, but its final characteristic of being substantially water insoluble, which is taught by Smith.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDC

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617